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March 24, 2004

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VIA CERTIFIED MAIL

Mr. Michael O. Leavitt, Administrator
U.S. Environmental Protection Agency
Ariel Rios Building – Room 1101A
1200 Pennsylvania Avenue N.W.
Washington, DC 20460

RE: SIXTY-DAY NOTICE OF INTENT TO SUE FOR FAILURE TO PERFORM NONDISCRETIONARY DUTY UNDER THE CLEAN AIR ACT.

Dear Mr. Leavitt:

This letter constitutes sixty-day notice of intent to commence a civil action pursuant to section 304(a)(2) of the Clean Air Act. The suit will be filed on behalf of the Missouri Coalition of the Environment (MCE) and Jack and Leslie Warden against the Administrator of the U.S. Environmental Protection Agency (EPA). The suit is based on EPA's failure to perform its nondiscretionary duty to review the national ambient air quality standard (NAAQS) for lead at least every five years as required by section 109(d)(1) of the Clean Air Act.

I. Statutory Requirements

Congress enacted the Clean Air Act "to protect and enhance the quality of the Nation's air resources so as to promote the public health and welfare and the productive capacity of its population." 42 U.S.C. § 7401(b)(1). In order to achieve this goal, the EPA must promulgate primary and secondary national ambient air quality standards (NAAQS) for criteria pollutants. *Id.* § 7409(a). These pollutants include: ozone, particulate matter, carbon monoxide, sulfur dioxide, nitrogen oxides, and lead. Primary NAAQS are intended "to protect the public health" with an adequate margin of safety. *Id.* § 7409(b)(1).

Because the NAAQS are science-based, the Clean Air Act requires the EPA to "complete a thorough review" of promulgated NAAQS at five year intervals, or more frequently if necessary, and revise the standards as appropriate to make sure that the standards reflect developments in scientific understanding in order to better protect public health. *Id.* § 7409(d)(1).

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EPA promulgated NAAQS for lead in 1978. EPA reviewed the NAAQS for lead once, in 1990. At that time, EPA did not revise the lead NAAQS. EPA has not reviewed the lead NAAQS since 1990, despite the clear Congressional mandate to do so.

II. Claim

The MCE and Jack and Leslie Warden intend to bring a citizen suit under the Clean Air Act, which authorizes any person to commence a civil action against the Administrator for the Administrator's failure to perform a nondiscretionary act or duty. 42 U.S.C. § 7604(a)(2).

Section 109(d)(1) of the Clean Air Act imposes a duty on the EPA to review, and if necessary revise, NAAQS at least every five years. It is well established that EPA's duty to review NAAQS every five years is a nondiscretionary duty, and is subject to a citizen suit such as this to compel an overdue NAAQS review. See, e.g. *American Lung Ass'n v. Reilly*, 962 F.2d 258, 263 (D.C. Cir. 1992) ("when...a statute sets forth a bright-line rule for agency action, such as in 42 U.S.C. § 7409(d)(1)...there is no room for debate—congress [sic] has prescribed a categorical mandate that deprives EPA of all discretion over the timing of its work."); *American Lung Ass'n v. Browner*, 884 F.Supp. 345, 346 (D.Ariz. 1994) ("Congress mandated fixed-date deadlines for the EPA to conduct the required reviews and if appropriate, to revise air quality criteria and ambient air quality standards.").

EPA has not reviewed the NAAQS for lead in over thirteen years. EPA has failed to perform its nondiscretionary duty to review NAAQS at least every five years.

III. Need for review of lead NAAQS

A. Health effects of lead

Lead is one of the most toxic substances to humans and serves no biological purpose in the human body. Its presence at even low levels in children can lead to many health problems including reduced IQ levels and behavioral problems, in addition to nervous system damage, anemia or even death. *Lead Toxicity*, United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Pub. ATSDR-HE-CS-2001-0001 (Rev. October 2000). Lead can also be passed from a pregnant woman to a fetus, which can lead to slow mental development, lower IQ levels, and premature birth. *Public Health Statement for Lead*, United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, CAS# 12709-98-7 (August 1997). Lead can also cause nervous system damage in adults. *Public Health Statement for Lead*, United States Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, CAS# 12709-98-7 (August 1997).

B. Derivations of the Lead NAAQS

Scientific developments make clear that the 1978 NAAQS for lead does not satisfy the conditions of section 109(b) of the Clean Air Act.

1. New Centers for Disease Control standard for blood lead level in young children

In initially establishing NAAQS for lead in 1978, the EPA first identified young children between the ages of one and five years old as the most sensitive population to lead exposure. National primary and secondary ambient air quality standard for lead, 43 Fed. Reg. 46246, 46252 (Oct. 5, 1978). Next, the EPA set a maximum safe blood lead level for young children at 30 µg Pb/dl. *Id.* at 46252. This level was based on four factors including that "the maximum safe blood lead level should be no higher than the blood lead range characterized as undue exposure by the Center for Disease Control of the Public Health Service." *Id.* at 46253. The EPA also concluded that the population blood lead level, which is "measured as the geometric mean, must be 15 µg Pb/dl in order to place 99.5 percent of children in the United States below 30 µg Pb/dl." *Id.* at 46252. This population blood lead level was used to ensure an adequate margin of safety in calculations to determine the ultimate NAAQS for lead.

In 1991, after the last EPA review of NAAQS for lead, the Centers for Disease Control (CDC) lowered the threshold of concern, which is a level above which known adverse health effects exist, for blood lead levels to 10 µg Pb/dl. *Preventing Lead Poisoning in Young Children*, Centers for Disease Control (1991). This level is one third of the "maximum safe blood lead level" used by EPA in setting NAAQS in 1978. This level is also lower than EPA's "population blood lead level," which was used to ensure an adequate margin of safety. Furthermore, recent studies demonstrate intellectual impairment in children at levels below 10 µg Pb/dl. Canfield et al., *Intellectual impairment in children with blood lead concentrations below 10 microg per deciliter*, New England Journal of Medicine, April 2003, at 1517-1526.

2. New studies on relationship between air lead and blood lead levels

In calculating the 1978 lead NAAQS, EPA also examined the relationship between exposure to air lead and the resulting blood lead level. 43 Fed. Reg. at 46254. After examining studies of the relationship between air and blood lead by Azar et al., Griffin et al., and Yankel et al, EPA used an air lead to blood lead ratio of 1 µg Pb/m^3 air to 2 µg Pb/dl blood (1:2), which was also used in EPA's 1990 review of lead NAAQS. EPA noted that the air to blood lead ratios ranged from 1:1 to 1:2, but also stated "that there are suggestive data indicating that the ratios for children are in the upper end of the range and may even be slightly above it." *Id.* at 46254. As young children between the ages of 1 and 5 are the most sensitive population, EPA must base lead NAAQS calculations on the air to blood lead ratios for children in order to adequately protect the health of this population.

Review of the scientific developments since 1978 and 1990 regarding the relationship between air lead and blood lead ratios shows a range of air to blood lead ratios between 1:1 and 1:6. The average ratio of air to blood lead in these studies lies between 1:3 and 1:4. Focusing on those studies including only children, the ratio lies between 1:3 and 1:6. When used in EPA's calculation of lead NAAQS, such a change in air to blood lead ratio would result in a substantial decrease in the NAAQS for lead.

IV. Conclusion

The Clean Air Act requires EPA to review NAAQS at least every five years. 42 U.S.C. § 7409(d)(1). EPA has a mandatory and nondiscretionary duty to ensure that these standards are reviewed and, if necessary, revised, in order to protect the health and welfare of the public. EPA has clearly failed to perform this duty by failing to review the NAAQS for lead for over thirteen years despite a clear and present need for review and revision evident by, among other things, the lowering of the CDC safe blood lead level and by numerous studies indicating increased air to blood lead ratios.

In light of the clear need for a prompt review and revision of lead NAAQS, we are interested in resolving this issue without judicial intervention. We hope that this notice will encourage the EPA to address a problem, which it has overlooked for over eight years, to the detriment of the health of the American public, especially those under six years of age. You may reach us at the contact information below.

Sincerely,

Interdisciplinary Environmental Clinic

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Attorneys for the Missouri Coalition of the Environment and Jack and Leslie Warden

cc: John Ashcroft, Attorney General
U.S. Department of Justice